Remarks

The Examiner has required, under 35 U.S.C. § 121, restriction to one of the following four groups of inventions:

Group I Claims 1-5, 7, 9-18, as specifically drawn to a compound comprising a bifunctional fusion glycoprotein or bifunctional glycoprotein conjugate, the compound comprising a carbohydrate complement, and: a) a fist portion which is an enzyme; b) a second portion which binds specifically to an epitope of a tumor specific antigen; wherein the carbohydrate complement comprises at least one exposed terminal carbohydrate residue, classified in class 530, subclass 350.

Group II Claims 1-5 and 8-18, as specifically drawn to a compound comprising a bifunctional fusion glycoprotein or bifunctional glycoprotein conjugate, the compound comprising a carbohydrate complement, and: a) a first portion which is an antibody; and b) a second portion which binds specifically to an epitope of a tumor specific antigen; wherein the carbohydrate complement comprises at least one exposed terminal carbohydrate residue, classified in class 530, subclass 391.1.

Group III Claim 19, as specifically drawn to a method of treating a tumor in a subject, comprising the steps of: a) administering in a first step a pharmaceutical preparation comprising a bifunctional hsion glycoprotein or bifunctional glycoprotein conjugate; b) administering in a second step a non-toxic prodrug that will subsequently be cleaved into a cytotoxic drug at the site of the tumor by the first portion, so that the tumor will regress thereby, classified in class 424, subclass 178.1.

Group IV Claims 20-21, as specifically drawn to a process of making a fusion glycoprotein, classified in class 530, subclass 395.

The Examiner alleges that the restriction is proper as the inventions are distinct, each from the other. In particular, the Examiner alleges that:

The inventions of Group I and II are unrelated.... In the instant case, the different inventions have a materially different design. For example, the bifunctional fusion glycoprotein of Group I comprises a first portion which is an enzyme, wherein the bifunctional fusion glycoprotein of Group II comprises a first portion which is an antibody.

Furthermore, the materially distinct products require separate and distinct searches. The nventions of Groups I and II have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-II.

The invention of Groups I-II and Group IV are related as process of making and product made...In the instant case the product of Group I or II could be made by a materially different process, such as isolation of a naturally occurring or cell cultured protein and chemical conjugation of the product.

> The inventions of Groups I-II and Group III are related as product and process of use… In the instant case the process of using the product as claimed in Group III can be practiced with another materially different product, such as a bifunctional fusion glycoprotein comprising an enzyme as the first portion or an antibody as the first portion.

Applicants respectfully traverse the Examiner's Restriction Requirement on Groups I and II.

First of all, the Group I and Group II claim the same invention. The key concept is that the protein which possesses enzymatic activity can be an enzyme or a catalytic antibody. In another twist, if a catalytic antibody is the protein with enzymatic activity and catalytic ability, it can be categorized to be an enzyme . In this instance, Claim 8, which claims a compound wherein the enzyme is a catalytic antibody, is to describe a species of the enzyme in Claim 6 and it narrows the scope of Claim 6. The subject matters of Claim 6 necessitates to include the subject matters of Claim 8. It is improper to state that "the bifunctional fusion glycoprotein of Group I comprises a first portion which is an enzyme, wherein the bifunctional fusion glycoprotein of Group II comprises a first portion which is an antibody". In fact, the Claim 1 clearly claim "at least one first portion which processes enzymatic activity". Therefore, the first portion of bifunctional fusion glycoprotein conjugate of Claim 1 can be enzyme (Claim 6) and/or catalytic antibody (Claim 8). Therefore, Groups I and II must be examined together.

Furthermore, Applicants submit that the inventions of Groups I and II do not impose a serious search burden on the Examiner because when "enzyme" is searched, it is bound to reveal information concerning protein catalysts including catalytic antibody with enzymatic activity. For this additional reason, Applicants maintain that the claims of Groups I and II should be examined together.

Applicants also Applicants respectfully traverse the Examiner's Restriction Requirement on Groups I, II, III and IV.

Applicants do not dispute that Groups I-II, IV and III are related as products, process of making and the method of use. However, Applicants point out that the mere existence of two or more independent or distinct inventions in one application is not sufficient to justify a restriction requirement. According to the guidelines in MPEP §803, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions. In particular, since Groups I-II claim products, and Group IV and III are related to processes of making and methods of using such products, a search for the claimed products of Groups I-II is bound to reveal information concerning their process of making and their method of use. Therefore,

performing the search covering the products, their process of making and method of use would not be a serious burden on the Examiner. Applicants maintain that the claims should be examined together.

To comply with the Restriction Requirement, Applicants provisionally elect, with traverse, Group I (Claims 1-5, 7 and 9-18). To comply with the Examiner's Election of Species Requirement, Applicants also provisionally elect β-glucuronidase for Claim 7 of Group I and anti CEA for Claim 9 of Groups I and II. Applicants affirm that Group III, which is drawn to a method of using, and Group IV, which is drawn to a process of making, may be subject for rejoinder if Group I is allowable. Applicants affirm their right to file one or more divisional applications with respect to any of the non-elected subject matter. In view of the aforesaid, Applicants respectfully request the reconsideration and withdrawal of the Restriction Requirement, especially regarding Groups I and II.

Applicants believe there are no fees due for this response, however, the Commissioner is authorized to charge the proper fee or credit any overpayment necessitated by this response to Deposit Account No. 18-1982.

Respectfully submitted,

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